K112064

MAR 2 3 2012

510(K) SUMMARY

Section 21CFR 807.92(a)

Submitter:

KLS-Martin, L.P.
11201 St. Johns Industrial Parkway South
Jacksonville, FL 32246
Phone: 904-641-7746
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Contact Person:

Jennifer Damato
RA/QA Director

Date of Summary:

October 28, 2011

Device Name:

KLS Martin Resorb-X G

Trade Name:

Resorb-X G

Classification:

Class II, §872.4760- Bone Plate

Product Code:

JEY

Predicate Devices:

SonicWeld RX (Resorb-X) **(K080862)**
Synthes (USA) Rapid Resorbable Fixation System **(K062789)**
Biomet, Inc. Lactosorb Trauma Plating System **(K992355)**

Device Description:

KLS Martin Resorb-X G is a resorbable fixation system similar to the SonicWeld-RX (Resorb-X) (K080862). The system consists of plates, meshes and pins manufactured in a variety of diameters and geometrical configurations that provide fixation and aid in the alignment and stabilization of fractures and reconstructive procedures. Resorb-X G is implanted utilizing ultrasonic force generated by an ultrasonic unit that causes a phase transition in the pin, allowing the pin to adapt to the previously drilled pilot hole in the surgical site and utilize the micro undercuts of the bone for retention.

Intended Use:

The KLS Martin Resorb-X G is intended for use in non-load bearing fracture repair and reconstructive procedures in adolescent and adult populations. In addition, resorbable meshes, plates and pins may be used in non-loading bearing applications for maintaining the relative position of, and/or containing, bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in oral and maxillofacial reconstruction.

Contraindications:

These devices are not intended for use in load bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. Resorb-X G is not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.

Technological Characteristics:

Similarities to Predicate

Resorb-X G uses the same pins, screws, and plates as SonicWeld-RX (Resorb-X) and is implanted in the same manner. The indication for use is the same as SonicWeld-RX (Resorb-X) K080862.

Differences to Predicate

Resorb-X G (PLLA/PGA) material differs in chemical composition from the SonicWeld-RX (Resorb-X) (PDLLA) material, but is the same as that in K062789 and K992355.

Performance Testing:

Chemical analysis to ISO 10993-12, -18 and mechanical degradation comparison testing for PDLLA vs. PLLA/PGA were submitted to demonstrate product safety and effectiveness.

Substantial Equivalence:

Performance testing results demonstrate that Resorb-X G (PLLA/PGA) is substantially equivalent to Resorb-X (PDLLA) and does not raise new issues of safety or effectiveness.

Material:

Poly(L-lactide-co-glycolide) (PLLA/PGA)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 2 3 2012

Ms. Jennifer Damato
Director of Quality Management & Regulatory Affairs
KLS-Matrin L.P.
11201 Saint Johns Industrial Parkway South
P.O. Box 16369
Jacksonville, Florida 32245-6369

Re: K112064
Trade/Device Name: Resorb-X G
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: March 12, 2012
Received: March 13, 2012

Dear Ms. Damato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112064

Indications for Use

SECTION 4

510(k) Number (if known): _____

Device Name: Resorb-X G

Indications for Use:

The KLS Martin Resorb-X G is intended for use in non-load bearing fracture repair and reconstructive procedures in adolescent and adult populations. In addition, resorbable meshes, plates and pins may be used in non-load bearing applications for maintaining the relative position of, and/or containing, bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in oral and maxillofacial reconstruction.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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